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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,479	11/22/2000	Doris Coit	PP01617.002	2173

7590 03/11/2003  
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EXAMINER

BROWN, STACY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 03/11/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/721,479

Applicant(s)

COIT ET AL.

Examiner

Stacy S Brown

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,4-19 and 32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4-19 and 32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 28, 2002 has been entered.
2. Claims 1, 4-19 and 32 are pending and examined on the merits. The drawings submitted November 27, 2002 are being considered by the Draftsperson.

### *Response to Arguments*

3. Applicant's arguments have been fully considered but fail to persuade. Claims 1, 4-19 and 32 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bartenschlager *et al.* (*Journal of Virology* (1993) 67:3835-3844) in view of Houghton *et al.* (EP 0693687) and Miyamura *et al.* (U.S. Patent 5,372,928) for reasons of record.

The amended claims are drawn to an isolated mutant NS HCV polypeptide having a C-terminal portion of NS3 and a deletion of at least 200 amino acids from the N-terminus of NS3. The recites that the deletion functionally disrupts the catalytic domain of NS3. The specification defines the catalytic domain as the protease active site (page 11, lines 19-20).

#### Applicant mainly argues that:

- *Bartenschlager fails to teach or suggest a polypeptide having a deletion of at least 200 amino acids from the N-terminus.*

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- In response, the Office acknowledges that Bartenschlager fails to teach a deletion of at least 200 amino acids from the N-terminus of HCV NS3, and that the reasons for the lack of protease activity are not clear (page 3840, col. 2).

However, Bartenschlager demonstrates (Figure 5) that a deletion of 60 amino acids rendered the protease non-functional. Regardless of the reasons for rendering the protease non-functional, (disrupting proteinase activity or accessibility of the cleavage site or both), Bartenschlager shows disruption. The polypeptide of Bartenschlager and the claimed polypeptide are functional equivalents, since both polypeptides contain the deletion that disrupts catalytic activity.

- *There is no motivation to use Bartenschlager's deletion mutant in a pharmaceutical composition. NS3 extends from approximately amino acids 1027-1657 (specification, page 27, line 30), and the claimed polypeptide's NS3 is lacking amino acids 1027-1227. Therefore, one or more epitopes may be lacking in the immunodominant region.*

- In response, a deletion of at least 200 amino acids from the NS3 region may eliminate the epitopes in the immunodominant region according to the specification, which discloses that amino acids 1207-1278 of NS3 (page 3) may represent an immunodominant region for CD4+ T cells. Even if the immunodominant region were deleted, other epitopes remain; otherwise the polypeptide would not be effective for inducing a therapeutic immune response. One of ordinary skill in the art would have been motivated to use the claimed deletion mutant in a composition because Houghton used an NS3 deletion mutant.

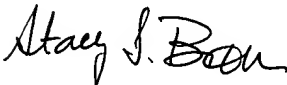
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*Conclusion*

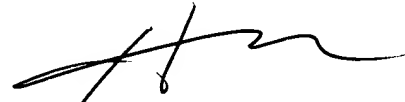
4. No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 located in Crystal Mall 1. The Fax number for Art Unit 1648 is (703) 308-4426. All Group 1600 Fax machines will be available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Stacy S. Brown, whose telephone number is (703) 308-2361. The Examiner can normally be reached on Monday through Friday from 6:30 AM-4:00 PM, (EST). If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, James C. Housel, can be reached at (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Stacy S. Brown  
March 6, 2003



HANKYEL T. PARK, PH.D  
PRIMARY EXAMINER